229. (New) The method of claim 224, wherein the antibody comprises a native antibody.

230. (New) The method of claim 210, wherein the antigen is CA125.

231. (New) The method of claim 230, wherein the level of CA125 in the host's serum is greater than 100 U/ml.

232. (New) The method of claim 210, wherein the binding agent is present in the composition in an amount of from 0.1 μg to 2 mg per kg of body weight of the host.

233. (New) The method of claim 210, wherein the binding agent is present in the composition in an amount of from 1 μg to 200 μg per kg of body weight of the host.

234. (New) The method of claim 210, wherein forming a binding agent/antigen complex presents other epitopes on the antigen to the host's immune system.

REMARKS

Claims 113, 115-135, 137-144, and 170-209 are pending.

Claim 176 has been canceled.

Claims 171 and 207 have been amended to correct regretted typographical errors. Claim 174 has been amended to incorporate the limitations of claim 176. Pursuant to the provisions of 37 C.F.R. §1.121(c)(1)(ii), a marked-up copy of amended claims 171, 174, and 207 is attached herewith as Appendix A.

Claims 210-234 have been added to cover methods for inducing a therapeutic host immune response comprising administering a composition comprising an antigen and a binding agent that specifically binds to that antigen. Support for these new claims can be found throughout the Application as filed; particularly at page 12, lines 16-18; at page 17, lines 13-18; at page 21, lines 22-25; at page 22, lines 26-29; at page 41, line 26 through page 42, line 4; at page 79, line 30 through page 80, line 18; and in Figures 4 and 5.

None of the above amendments adds any new matter to the Application as filed.

I. Priority

The Office Action has asserted that the filing receipt claims this Application to be a CIP of 09/376,604 (which is the serial number of this Application).

Applicants enclose herewith as Appendix B a copy of the corrected filing receipt which lists the correct priority of the Application. As the corrected filing receipt indicates, this Application is a continuation-in-part of International Application No. PCT/IB96/00461 filed May 15, 1996; a continuation-in part of U.S. Serial No. 08/877,571 filed June 17, 1997 (now U.S. Patent No. 6,086,873); a continuation-in-part of U.S. Serial No. 09/094,598 filed June 15, 1998; a continuation-in-part of U.S. Serial No. 09/152,698 filed September 2, 1998, and a continuation-in-part of PCT/IB99/01114 filed June 15, 1999. However, as the corrected filing receipt indicates, this Application does not claim to be a CIP of 09/376,604.

Applicants note for the record that PCT/IB96/00461 (filed May 15, 1996) is not a CIP of 08/877,302, which is not a CIP of 09/094,598 (filed June 15, 1998), which is not a CIP of 09/152,698 (filed Sept. 2, 1998), which is not a CIP of PCT/IB99/01114 (filed June 15, 1999). Rather, the Application, as stated on the filing receipt and on the page 1 of the specification, claims to be a CIP of each of International Application No. PCT/IB96/00461 filed May 15, 1996; U.S. Serial No. 08/877,571 filed June 17, 1997 (now U.S. Patent No. 6,086,873); U.S. Serial No. 09/094,598 filed June 15, 1998; U.S. Serial No. 09/152,698 filed September 2, 1998, and a PCT/IB99/01114 filed June 15, 1999.

II. 35 U.S.C. §112, First Paragraph, Rejections

Claims 113, 115-135, 137-144, and 170-209 stand rejected under 35 U.S.C. §112, first paragraph, because the specification does not provide evidence that the claimed biological materials are known and readily available to the public, reproducible from a written description, or deposited (Office Action, page 2).

Applicants respectfully traverse this ground for rejection.

As agent of record, I declare the following. Applicants have deposited the hybridoma producing the monoclonal antibody, B43.13, with the American Type Culture Collection (ATCC) in accordance with the provisions of the Budapest Treaty. Attached as Appendix C is a copy of the deposit receipt from the ATCC. As can be seen, the ATCC has assigned B43.13 the

despot number of PTA-1883. All restrictions upon public access to the deposits were irrevocably removed when U.S. Patent No. 6,241,985 was granted on June 4, 2001.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this ground for rejection.

III. 35 U.S.C. §102 Rejections

Claims 113, 115-126, 128-132, 135, 137-140, 174-188, 190-194, 196, and 201-205 stand rejected under 35 U.S.C. §102 as being as being anticipated by Madiyalakan *et al.*, Hybridoma 14(2): 199-203, 1995 ("Madiyalakan").

Applicants respectfully traverse this ground for rejection.

As this rejection applies to independent claims 113, 135, and 201, and the claims dependent upon these independent claims (namely claims 115-126, 128-132, 137-140, and 202-205), Applicants respectfully note that a required limitation of all these claims is not met in Madiyalakan. Specifically, each of claims 113, 135, and 201 requires the use of a non-radiolabeled binding agent in the claimed method. In contrast, the binding agent administered in the method of Madiyalakan is radiolabeled antibody B43.13 (see, *e.g.*, third full paragraph on page 200, left column; second full paragraph on page 201, left column; and footnotes to Table 1 on page 200, Figures 3 and 4 on page 201 and Figure 5 on page 202). Because Madiyalakan fails to teach a required limitation of claims 113, 135, and 201, Madiyalakan cannot anticipate these claims nor the claims dependent upon claims 113, 135, and 201.

As this rejection applies to claim 174-188, 190-194, and 196, Applicants have overcome this ground for rejection with the present amendment to claim 174 (upon which claims 175-188, 190-194, and 196 depend), adding the limitation that the binding agent present in the composition of the claimed method be non-radiolabeled. As discussed above, Madiyalakan does not teach administration of a non-radiolabeled binding agent.

Failing to teach a required limitation of the claims, Madiyalakan cannot anticipate any of claims 113, 115-126, 128-132, 135, 137-140, 174-188, 190-194, 196, and 201-205. Accordingly, Applicants respectfully request reconsideration and withdrawal of this ground for rejection.

IV. 35 U.S.C. §103 Rejections

Claims 113, 115-135, 137-144, and 170-209 stand rejected under 35 U.S.C. §103 as being unpatentable over Madiyalakan in view of Baum *et al.*, Hybridoma 12(5): 583-589, 1993 ("Baum I") or Baum *et al.*, Cancer Supplement 73(3): 1121-1124, 1994 ("Baum II").

Applicants respectfully traverse this ground for rejection.

All of claims 113, 115-135, 137-144, and 170-209 require a binding agent that is non-radiolabeled for use in inducing a therapeutic host immune response. As discussed above, Madiyalakan teaches administration of a composition comprising a binding agent that is radiolabeled. Nowhere does Madiyalakan teach or suggest administration of a non-radiolabeled binding agent.

In addition, neither of Baum I or Baum II teaches or suggests administration of a non-radiolabeled binding agent to induce a therapeutic host immune response. Baum I describes the administration of antibodies radiolabeled with ^{131}I, ^{111}In, or ^{99m}Tc (see abstract and first paragraph on page 583, and Table I on page 584). Although the labeling efficiency is slightly less than 100%, Baum I makes the strong suggestion that a superior immune response is achieved with an antibody that has better imaging capabilities (*i.e.*, a radiolabeled antibody) (see paragraph spanning pages 583-584). Thus, Baum I teaches away from the use of a non-radiolabeled binding agent to induce a therapeutic immune response.

Baum II likewise neither teaches or suggests administration of a non-radiolabeled binding agent, as is required by the claims. Baum II discloses the administration of Indium-111-labeled F(ab') antibody fragment and the administration of technetium-99m-labeled intact antibody (page 1122, left column, second full paragraph). Nowhere does Baum II teach or suggest the administration of a non-radiolabeled binding agent for any purpose, much less for the purpose of inducing a therapeutic immune response.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this ground for rejection.

V. Double Patenting

Claims 113, 115-135, 137-144, and 170-209 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,241,985.

To overcome this ground for rejection, Applicants submit herewith a Terminal Disclaimer pursuant to the provisions of 37 C.F.R. §1.321, disclaiming any portion of the term of any patent granted on this Application which would extend beyond the expiration of U.S. Patent No. 6,241,985.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this ground for rejection.

CONCLUSION

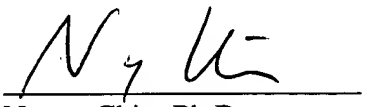
For the reasons stated above, Applicants respectfully submit that the claims are now ready for allowance. If the Examiner believes that any further discussion of this communication would be helpful, she is encouraged to contact the undersigned by telephone.

As the number of new claims is below the number of claims previously paid for by the Applicants when the Application was filed, Applicant believes no fee is due for the addition of the new claims.

In accordance with the provisions of 37 C.F.R. §1.136(a)(1), Applicants enclose herewith a petition requesting a one month extension of time up to and including October 19, 2001 to respond to the Office Action. Please apply the one month extension of time fee of $55.00 to our Deposit Account No. 08-0219. This fee amount reflect the Small Entity Status of the Application, which remains proper.

No additional fees are believed to be due in connection with this communication. However, please apply any additional charges, or credit any overpayment, to our Deposit Account No. 08-0219.

Respectfully submitted,
HALE AND DORR LLP



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Date: October 18, 2001

APPENDIX A

Marked-up Version of the Amended Claims Pursuant to 37 C.F.R. §1.121(c)(1)(ii)

171. (Amended) The method of claim 135, wherein [contacting comprises administering] the composition is administered by any immunologically suitable route.

174. (Amended) A method for inducing a therapeutic host immune response against a multi-epitopic *in vivo* antigen that does not elicit an effective host immune response, the method comprising contacting a multi-epitopic *in vivo* antigen present in a host's serum with a composition comprising a binding agent that specifically binds to an epitope on the antigen, the binding agent present in the composition being non-radiolabeled, and allowing the binding agent to form a binding agent/antigen complex, wherein the binding agent/antigen complex elicits an effective host immune response against the multi-epitopic *in vivo* antigen.

207. (Amended) The method of claim 201, wherein [contacting comprises administering] the composition is administered by any immunologically suitable route.

APPENDIX B

CORRECTED FILING RECEIPT